House of Commons

Science and Technology Committee

DEVELOPMENTS IN HUMAN GENETICS AND EMBRYOLOGY

Fourth Report of Session 2001–02

HC 791

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Science and Technology Committee

DEVELOPMENTS IN HUMAN GENETICS AND EMBRYOLOGY

Fourth Report of Session 2001–02

Report, together with Proceedings of the Committee, Minutes of Evidence and Appendices

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Footnotes

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FOURTH REPORT

The Science and Technology Committee has agreed to the following Report:

DEVELOPMENTS IN HUMAN GENETICS AND EMBRYOLOGY

Introduction

1. Our Committee has taken a long-standing interest in medical genetics research and its application. Our predecessor Committee's 1995 Report on *Human Genetics: the Science and its Consequences* followed an extensive and wide-ranging inquiry and anticipated many of the issues that lay ahead in this field.[1] In 2001 our predecessors reported on *Genetics and Insurance*, recommending a moratorium on the use of positive genetic tests by insurers and highlighting a number of problems with the existing regulatory framework in this area.[2] Their 2001 report on *The Scientific Advisory System* discussed the role of the Human Genetics Commission (HGC) as part of a wider examination of government scientific advisory committees.[3] In March 2002 we held a seminar with leading researchers in the fields of embryology and stem cell research to discuss the policy and regulatory implications of recent advances of research using embryos.[4] It is our intention to monitor developments in this area over the course of the Parliament.

2. On 24 April 2002 we took oral evidence from Dame Ruth Deech, former Chair of the Human Fertilisation and Embryology Authority (HFEA), Helena Kennedy (Baroness Kennedy of the Shaws), Chair of the HGC, and Suzi Leather, Chair of the HFEA. Dame Ruth, a family and property lawyer, was Chair of the HFEA from 1994 to 2002. She was replaced in April 2002 by Ms Leather, who has a background in consumer representation on health, food and agricultural issues and is also Deputy Chair of the Food Standards Agency. Baroness Kennedy is a criminal lawyer and has chaired the HGC since its foundation in December 1999. The transcript of this evidence session is printed with this Report, together with supplementary evidence provided by the HFEA, Professor Robin Lovell-Badge, from the National Institute for Medical Research, Dame Anne McLaren from the Wellcome Trust/Cancer Research UK Institute of Cancer and Developmental Biology and Professor Austin Smith from the Centre for Genome Research at Edinburgh University.[5]

3. This short Report draws attention to particular areas of concern raised by the witnesses, follows up on issues raised by inquiries from our predecessor Committees and makes recommendations to Government where action is urgently needed. Later this year the Government will publish its Green Paper on Genetics, to examine "the ethical, clinical, scientific and economic issues" surrounding genetics.[6] **We welcome the intended breadth of the forthcoming Green Paper on Genetics and hope it embraces the views we express in this Report.**

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[1] Third Report of the Science and Technology Committee, Session 1994-95, *Human Genetics: the Science and its Consequences*, HC41-I

[2] Fifth Report of the Science and Technology Committee, Session 2000-2001, *Genetics and Insurance*, HC 174

[3] Fourth Report of the Science and Technology Committee, Session 2000-2001, *The Scientific Advisory System*, HC 257

[4] This took place on 13 March 2002. The Committee heard from Dame Anne McLaren, Cambridge University; Professor Austin Smith, Edinburgh Centre for Genome Research; Professor Robin Lovell-Badge, National Institute for Medical Research; and Dr Alan Colman, PPL Therapeutics.

[5] Ev 1-14

[6] Speech by Rt Hon Alan Milburn MP, Secretary of State for Health, 19 April 2001

Organisations and their structures

Human Fertilisation and Embryology Authority

Background

4. The HFEA was established in 1991 by the Human Fertilisation and Embryology Act 1990.[7] It is an executive non-departmental public body sponsored by the Department of Health and has a staff of around 30. No research on human embryos may be undertaken except under licence from the HFEA. It also licenses all UK treatment clinics offering in-vitro fertilisation or donor insemination, or storing eggs, sperm or embryos.

Income and expenditure

5. The HFEA generates income by charging fees to in-vitro fertilisation centres holding licences. It is set an expenditure limit (£1,575,000 in 2000-01). The Department of Health and the devolved administrations fund the difference between the levied charges (£1,242,000 in 2000-01) and this expenditure limit.[8] The funding mechanism ensures that the HFEA's income remains the same whatever the income raised by fees, and therefore that it has no direct incentive to award licences. Given the importance of avoiding such an incentive, it is curious that the Department of Health has set a target for the HFEA to raise 70% of its income from fees. (In practice, it has exceeded this target: between 1994-95 and 2000-01 the HFEA raised 88% of its expenditure through fees, and in 1998 and 2000 made a profit.)[9] The overall expenditure limit has presumably been set at the level the Department of Health thinks has been necessary for the HFEA, though how this figure has been reached is unclear.

6. Dame Ruth said that "If the HFEA were set up today, in the light of public fears about anything with the word "genetic" in it, whether it is BSE or genetically modified food or whatever, there would be a much more exhaustive approach. I believe that we have the least funding of any comparable organisation".[10] Ms Leather said that when she saw the budget for the first time she "thought they had got the decimal point in the wrong place".[11] In June 2002, the HFEA issued a consultation document on its future funding.[12] It states that the HFEA needs "ongoing operating funding of at least £4.5 million" to perform its licensing and regulatory functions.[13] (This is in addition to £3 million a year which it foresees will be needed for "information systems and accommodation".[14]) It cites scientific and clinical developments, public expectations and government policy as justifications for the increase. It states that the Department of Health has indicated that it will continue to provide £0.6 million baseline funding but that any increase in funding should come from licence fees.[15] (It is not clear whether the HFEA will be subject to an expenditure limit in the future.) The HFEA sets out for consultation two alternative ways of raising the

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7 See www.hfea.gov.uk
8 Ev 12-13
9 Income from licences issued for research is negligible (around £22,000). The HFEA is planning a consultation of the funding of its activities relating to research.
10 Q12
11 Q14
12 *HFEA Consultation on the Modernisation of Regulation and New Fee Strategy*, June 2002
13 *Ibid*, para 61
14 *Ibid*, para 62
15 *Ibid*, para 61

funding of £4 million from fees. **The HFEA is asking for its income to be more than doubled. We accept that its activities have increased in recent years but, for such a large increase, it needs to make a more detailed financial case than its consultation document provides. If it can prove the need for such a large increase, it should be met by increased contributions from Government as well as from licensees. We are concerned that the Government's insistence that any increase in funding should be met from licence fees alone undermines the principle that the HFEA should have no incentive to award licences.**

Performance

7. The HFEA has been largely successful in ensuring public confidence in its regulation of fertility treatments and research. The Lords Stem Cell Research Committee reported that the HFEA is "highly regarded, both at home and abroad ... [and] has the full confidence of the scientific and medical research community".[16] We are unclear on what evidence it based this assertion. While many of its problems can be explained by a lack of funding, some criticisms can be levelled against the organisation. Professor Austin Smith, a stem cell researcher at Edinburgh University, has found the HFEA to be "inefficient ... and lacking in specialist knowledge" and "a slow and reactive" body. Professor Smith has found the issue of consent forms particularly problematic: "The HFEA provides no guidelines for drawing up consent forms for embryo donors and gives no advice to the licence applicant".[17] Dr Robin Lovell-Badge indicates that researchers have found the HFEA frustrating to deal with and that there has been criticism from researchers regarding the time the HFEA takes to process licence applications.[18] Ms Leather said that the average time for research applications to be processed was four months.[19] We have been told that some applications have taken a good deal longer than this. We note that in the year 2000-01 the HFEA missed its targets for licence renewal (for both treatment and research) by some margin, especially for research licences, though we recognise the problems it has had with high staff turnover.[20] **Britain is well placed to be a world leader in human genetics and embryology research and it is crucial that our scientists, in complying with regulatory requirements, are not hampered by bureaucracy.**

8. The HFEA's communication strategy seems to be focused on licensees and patients. While this may be in part because of a lack of resources, the HFEA does not appear to have made much effort to communicate more widely, yet the public has a legitimate interest in its work and administration. Until recently, the HFEA's website reflected poorly on the importance it attached to transparency and accessibility. The new-look site is a step in the right direction. The recently published Annual Report for 2000-01 said that the second quinqennial review of the HFEA recommended that it adopt "more open and transparent working practices".[21] Suzi Leather said that "communicating what we are doing, communicating what the possibilities of science are, what the benefits and disbenefits are, is probably the core challenge for the HFEA".[22] **The HFEA's new emphasis on communication with the public is welcome. Continued public confidence demands that the HFEA takes the lead in encouraging awareness and debate about research and treatment involving human embryos.**

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16 House of Lords Stem Cell Research Committee, Session 2001-2002, HL 83(i), para 8.1
17 Ev 14
18 Ev 11
19 Q10
20 Tenth Annual Report and Accounts 2001, HFEA, annex 6, p. 39
21 *Ibid*, p.10
22 Q20

Human Genetics Commission

Background

9. The HGC was formed in 1999 as the result of a review of the advisory and regulatory framework for biotechnology conducted by the Office of Science and Technology and the Cabinet Office.[23] It took on the responsibilities of the former Advisory Committee on Genetic Testing, Advisory Group on Scientific Advances in Genetics and Human Genetics Advisory Commission.[24] The HGC is an advisory non-departmental public body under the Department of Health and Office of Science and Technology and has a secretariat of four drawn from these departments. Its brief is to analyse current and potential developments in human genetics and advise ministers; advise on strategic priorities in the delivery of genetic services by the NHS; advise on strategic priorities for research; and consult the public and other stakeholders and encourage debate on human genetic technologies.

Funding and activities

10. The HGC is funded by the Department of Health, with contributions from the Office of Science and Technology, National Assembly for Wales, Northern Ireland Assembly and the Scottish Executive. The HGC's total budget for 2000-01 was £425,000.[25] Our predecessor Committee recommended in 2001 that the Government should, with urgency, review the funding of the HGC.[26] The Government's response was disappointing, saying merely that it "is committed to keeping the resources available to all of its advisory bodies under review".[27] It is clearly a concern of Baroness Kennedy, who told us that "I am one of those people who, whenever I see a minister, never misses the opportunity of saying that we could do with more money".[28]

11. Much of the HGC's non-staff expenditure goes on committees and public events. A vital part of the HGC's work is to engage the public in discussion about issues in human genetics. Its terms of reference state that it should "develop and implement a strategy to involve and consult the public and other stakeholders and encourage debate on the development and use of human genetic technologies and advise on ways of increasing public knowledge and understanding". Baroness Kennedy told us that the HGC "did a consultation on the privacy issues around genetics and that cost us in the region of about £50,000".[29] Truly effective public consultation does not come cheap and the HGC's budget gives it little hope of generating better awareness of human genetics and addressing the public's concerns. **The Prime Minister said recently that he wishes to avoid a "retreat into a culture of unreason".[30] A good place to start would be to ensure that the Human Genetics Commission has access to sufficient funds to enable it to conduct an extensive and genuine dialogue with the public.**

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[23] *The Advisory and Regulatory Framework for Biotechnology: Report from the Government's Review*, Cabinet Office, Office of Science and Technology, May 1999

[24] See www.hgc.gov.uk

[25] Fifth Report of the Science and Technology Committee, Session 2000-01, *Genetics and Insurance*, HC 174, Appendix 26

[26] *Ibid*, para74

[27] *Government Response to the Report from the House of Commons Science and Technology Committee: Genetics and Insurance*, Cm 5286, para 48

[28] Q59

[29] Q50

[30] Speech made by the Prime Minister at the Royal Society on 23 May 2002

Advisory and regulatory framework

12. The foundation of the HGC had been recommended by our predecessor Committee in 1995 but our predecessors were disappointed that initially only an advisory committee, the HGAC, was set up. The Committee's recommendation in 1995 had been that the HFEA provided a good model for a Commission, with statutory regulatory powers combined with an advisory role and a research budget.[31] In its 2001 Report on the Scientific Advisory System, our predecessor Committee welcomed the establishment of the HGC but regretted that it had not been given statutory powers and expressed concern that "The status accorded different advisory bodies at present appears haphazard".[32]

13. Although the HGC replaced three advisory committees, it still leaves other advisory and regulatory bodies active in medical genetics: the Gene Therapy Advisory Committee and the Genetics and Insurance Committee. It could be argued that these should have been incorporated into the HGC in the first place. The plethora of advisory and regulatory bodies was a concern of the Committee in the last Parliament: "a lot of committees have grown up over the years, and ... they are not in any rational pattern".[33] In its recent report *Inside Information*, the HGC suggests that the division of responsibilities with the Genetics and Insurance Committee has not worked well.[34] **We recommend that the Government conduct a thorough review of advice and regulation across the fields of medical genetics, embryology and reproductive medicine, with a view to producing a more streamlined structure.**

Stem cells

14. Stem cells provide the potential to treat a wide range of diseases by virtue of their ability to differentiate and develop into a range of cell types. A technique called cell nuclear replacement (CNR), which was used to create Dolly the Sheep, offers the prospect of increasing our understanding of cellular processes and of creating stem cells with a particular genetic make-up, which may be of therapeutic value. Under the Human Fertilisation and Embryology Act 1990, as enacted, research on embryos for therapeutic purposes could not be licensed by the HFEA. In November 2000, following the recommendations of a report by the Chief Medical Officer (the Donaldson Report)[35], the Government laid draft Regulations before Parliament, allowing the HFEA to license research involving embryos for the purposes of (a) increasing knowledge about development of embryos, (b) increasing knowledge about serious disease and (c) enabling any such knowledge to be applied in developing treatment for serious disease. The draft Regulations were passed by both Houses and came into effect on 31 January 2001 as the Human Fertilisation and Embryology (Research Purposes) Regulations 2001.

15. The ProLife Alliance sought a judicial review of the 2001 Regulations, claiming that "human embryos created by cell nuclear replacement, which process does not involve 'fertilisation', do not satisfy the definition of 'embryo' in section 1 of the 1990 Act".[36] On 15 November 2001 the High Court granted a declaration in the terms sought, in effect

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[31] Third Report of the Science and Technology Committee, Session 1994-95, *Human Genetics: The Science and its Consequences*, HC41-I, paras 285-286

[32] Fourth Report of the Science and Technology Committee, Session 2000-2001, *The Scientific Advisory System*, HC 257, para 30

[33] *Ibid*, para 77

[34] *Inside Information: Balancing Interests in the Use of Personal Genetic Data*, a report by the Human Genetics Commission, May 2002

[35] *Stem Cell Research: Medical Progress with Responsibility*, Report of the Chief Medical Office's Expert Advisory Group on Therapeutic Cloning, Department of Health, August 2000

[36] R(Quintavalle) v Secretary of State for Health

removing embryos created by CNR from regulation by the HFEA. In response, and to ensure that CNR was not used for human reproductive cloning, the Government introduced the Human Reproductive Cloning Bill on 21 November, which became law on 4 December 2001. It provides that "A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence". At the same time the Government appealed against the High Court's judgment. On 18 January 2002 the Court of Appeal allowed the appeal, in effect bringing embryos created through the use of CNR within the scope of the 1990 Act. The ProLife Alliance has been given leave to appeal against this ruling to the House of Lords and a hearing is expected before the end of 2002.

16. During the debate on the Regulations on 22 January 2001, some members of the House of Lords were concerned about the speed with which legislation was being introduced and that the creation of cloned embryos could lead to human cloning (CNR could result in a cloned human if the resulting embryo were implanted in the womb). This was met by an amendment calling on the Government to support the appointment of a House of Lords Select Committee to report on the issues connected with human cloning and stem cell research, and to undertake to review the Regulations following the report of that Committee. The House of Lords Stem Cell Research Committee's report, published on 27 February 2002, affirmed the importance of this area of research and concluded that the current regulatory framework provided sufficient protection against the development of CNR leading to human reproductive cloning.[37] On 28 February 2002 the HFEA approved two applications for research on human embryos to produce stem cell lines, neither of which involves CNR.[38] The Government published its response to the Lords Committee on 4 July 2002.[39]

17. Embryonic stem cells are not considered to be embryos and do not fall within the remit of the HFEA.[40] Neither does the HFEA have jurisdiction over clinical trials involving adult stem cells. The Lords Committee suggested either that a new advisory committee be set up to regulate clinical studies on all types of stem cells or that the remit of the Gene Therapy Advisory Committee be extended.[41] The question arises, however, why not simply extend the remit of the HFEA to cover stem cell lines? The Lords Committee took the line that research on established stem cell lines did not require the level of regulation to which human embryo research is currently subject by the HFEA. This is true, but the HFEA could readily operate a 'lighter touch' regulatory regime for stem cell research. We note that Ms Leather showed no enthusiasm for the HFEA taking on this role[42] but in our view there would be benefit in avoiding the creation of yet another body in this already overcrowded regulatory field. The Government, in its response to the Lords Stem Cell Committee, says it will consider whether "further oversight of ... clinical trials involving embryonic stem cells is desirable" but highlights important differences between stem cell therapy and gene therapy.[43]

18. The Lords Committee endorsed the Department of Health's request to the Medical Research Council to establish a stem cell bank.[44] The MRC has set up a National Stem Cell Bank Advisory Committee which will choose an independent national laboratory as the location and oversee the bank once it has been established. Both Baroness Kennedy and Dame Ruth felt that the body that regulates clinical trials involving stem cells could include a cell bank within its remit.

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37 House of Lords Stem Cell Research Committee, Session 2001-2002, HL 83(i), para 5.24
38 From the Centre for Genome Research in Edinburgh and from Guy's Hospital in London.
39 Government Response to the House of Lords Select Committee Report on Stem Cell Research, July 2002, Cm 5561
40 HL 83(i), para 8.22
41 *Ibid*, para 8.23
42 Qq 32–43
43 Cm 5561, pp 16-17
44 HL 83(i), para 8.29

19. We recognise that different areas of expertise are needed to assess different areas of clinical research, but **the Government should operate from the principle that no more advisory and regulatory bodies should be created than are absolutely necessary and it is better to reinforce the success of existing bodies by extending their remit than to spawn ever more small specialised bodies.**

International perspectives

20. Modern medical science is a global activity. The negotiations for the European Commission's Framework Programme 6, in which some countries wished to limit the funding available for research on stem cells, demonstrate that countries with different cultural and religious backgrounds can take very different ethical stances.[45] In October 2001, the European Parliament's Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine visited Westminster.[46] It was clear from the discussion that there was considerable tension on the stem cell issue. The Council of Europe's Convention of Human Rights and Biomedicine was published in 1998. In permitting CNR, the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 are in conflict with Article 18 of the Convention, which prohibits the creation of cloned embryos for research. There is provision for a State to sign the Convention with a reservation where it is in conflict with existing legislation (Article 36), however. The UK is not a signatory to the Convention and we believe the Government should consider whether it should join as part of an international effort to prohibit human cloning. We note that the Government is supporting a draft UN convention to outlaw human reproductive cloning.[47] **We believe that the Government should remain active on the international stage, as well as domestically, in ensuring that scientific advances are facilitated yet appropriately balanced by regulatory and legislative control.**

Legislative framework

21. It is now 12 years since the Human Fertilisation and Embryology Act was enacted, and the science that informed it has been superseded. As Dame Anne McLaren says, "the HFEA seems to have a wider sphere of responsibility with every year that passes", presenting new challenges to the organisation.[48] Some of these issues create unease in some quarters. We asked the witnesses whether it was time to review the 1990 Act. Dame Ruth said that the Act might need to be amended to take account of human rights legislation and that there was too much emphasis on confidentiality in the Act (she told us that this made it difficult for the HFEA to get its computers repaired, for example).[49]

22. Baroness Kennedy also suggested an area where legislation was necessary. She believed that theft of DNA should become a criminal offence and that a new body should be set up to regulate DNA databases.[50] Already there are signs that inappropriate use of DNA is taking place and the BioBank initiative, the funding of which was announced on 29 April 2002,[51] has also raised concerns.[52] The HGC's recent report *Inside Information*

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[45] Q46
[46] The Committee met with members of our predecessor Committee (including members of the current Committee) and the House of Lords Science and Technology Committee.
[47] Cm 5561, pp 13
[48] Ev 12
[49] Q31
[50] Q62
[51] Joint news release issued by the Wellcome Trust, the Medical Research Council and the Department of Health
[52] HC Deb, 3 July 2002, cols 365-372

discusses this and many other issues surrounding the use of personal genetic data.[53] We are aware that some see a need for much stronger legislation in this area to protect genetic privacy, to prevent genetic discrimination and to regulate the commercial exploitation of genetic samples.[54]

23. Some witnesses told the Lords Stem Cell Research Committee that they believed the 2001 Regulations to be ultra vires the Human Fertilisation and Embryology Act in extending the Act to cover basic research. While the Stem Cell Committee did not believe this to be the case, it suggested new legislation to make "express provision for such basic research as is necessary as a precursor for the development of cell-based therapies".[55] In its response to the Stem Cell Committee, the Government said it had "no reason to believe that legislation will be required for the foreseeable future".[56] The Committee identified where scientific advances might require new legislation: the mixing of animal eggs with human cells; the dedifferentiation of adult stem cells to form the equivalent of a zygote (a fertilised egg) which could go on to form an embryo; the generation of an embryo from an oocyte (egg); the induction of differentiation using animal material; and the induction of embryonic stem cells into an embryo.[57] **The House of Lords Stem Cell Research Committee has identified several areas which might require new legislation. The Government should work on the premise that these developments will happen sooner rather than later and introduce legislation accordingly.**

24. The ProLife Alliance is appealing to the House of Lords over the High Court's decision that embryos formed by CNR are covered by the HFE Act. This would leave any embryo formed by means other than by fertilisation completely unregulated, although the Human Reproductive Cloning Act has made illegal the implantation of such an embryo in the womb. The Government remains "satisfied that any embryo research that used CNR is covered by the 1990 Act".[58] **Should the ProLife Alliance's appeal to the House of Lords be successful, we urge the Government to introduce new legislation to bring the creation of embryos by whatever means within the remit of the 1990 Human Fertilisation and Embryology Act.**

25. On 13 December 2001, the HFEA decided to allow tissue typing in conjunction with preimplantation genetic diagnosis (PGD) for serious genetic diseases. This decision led to a clinic being awarded a licence from the HFEA to implant an embryo with a genetic profile that would enable the baby to donate bone marrow to an older sibling with beta thalassaemia. Questioned on the decision, Dame Ruth asserted that "The public has been consulted about preimplantation genetic diagnosis".[59] The consultation of which she spoke was begun in November 1999 by the HFEA and the former Advisory Committee on Genetic Testing. Yet this did not address the issue of tissue typing to benefit an existing family member. Indeed, the HFEA/HGC Joint Working Party set up in December 2000 to consider the results of the consultation specifically ruled out such a procedure, stating in its report that "there were sufficient ethical difficulties with this approach that it should be subject to further discussion".[60] Further discussion did indeed take place before a decision was made, but only within the HFEA's own ethics committee.[61] **The HFEA's decision to allow tissue typing in conjunction with preimplantation genetic diagnosis went**

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[53] *Inside Information: Balancing Interests in the Use of Personal Genetic Data*, a report by the Human Genetics Commission, May 2002

[54] Response to HGC consultation on personal genetic information from Human Genetics Alert, see ww.hgalert.org

[55] HL 83(i), para 8.10-8.15

[56] Cm 5561, pp 16

[57] HL 83(i), paras 8.18-8.19

[58] Cm 5561, pp 6

[59] Q7

[60] *Outcome of the Public Consultation on Preimplantation Genetic Diagnosis*, HGC/HFEA, November 2001, paragraph 29

[61] *Ethical Issues in the Creation and Selection of Preimplantation Embryos to Produce Tissue Donors*, Ethics Commitee of the HFEA, November 2001

beyond the scope of its own public consultation. It is vital that the public are taken along with decisions of such ethical importance.

26. We take issue with Dame Ruth's assertion that the fact that the HFEA took the decision on PGD "protects Members of Parliament from direct involvement in that sort of thing".[62] Parliament does not need protecting and democracy is not served by unelected quangos taking decisions on behalf of Parliament. A pressure group, Comment on Reproductive Ethics, is seeking judicial review in the High Court on PGD on the grounds that the 1990 Act only permits distinguishing between embryos on the basis of whether they are healthy or not or for providing treatment services to the mother. Should this ultimately be successful, Parliament's intervention may be inevitable.

27. The Government has recently been conducting a consultation on the question of introducing new Regulations under the HFE Act to enable the offspring resulting from donated sperm, eggs or embryos to learn the identity of the donor. The issue was considered in Parliament during the passage of the Act but this may be another area that needs an overhaul.

28. Dame Ruth felt that new legislation on human embryology risked becoming "enmeshed with opponents of abortion".[63] This may be true but we cannot accept that Parliament should not be asked to consider major ethical issues for fear that elected representatives might come to a view that is different from that of the scientific community. The debates that took place on the Human Fertilisation and Embryology (Research Purposes) Regulations in December 2000 (Commons) and January 2001 (Lords), and on the Human Reproductive Cloning Bill in December 2001 showed that Parliament is well capable of considering these sensitive subjects sensibly. **The Government's apparent reluctance to enact new legislation in this sensitive area has led to a position where the 1990 Act is open to legal challenge. We recommend urgent action to remedy this and reconnect the Act with modern science**.

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[62] Q5
[63] Q33

LIST OF RECOMMENDATIONS AND CONCLUSIONS

1. **We welcome the intended breadth of the forthcoming Green Paper on Genetics and hope it embraces the views we express in this Report (paragraph 3).**

2. **The HFEA is asking for its income to be more than doubled. We accept that its activities have increased in recent years but, for such a large increase, it needs to make a more detailed financial case than its consultation document provides. If it can prove the need for such a large increase, it should be met by increased contributions from Government as well as from licensees. We are concerned that the Government's insistence that any increase in funding should be met from licence fees alone undermines the principle that the HFEA should have no incentive to award licences (paragraph 6).**

3. **Britain is well placed to be a world leader in human genetics and embryology research and it is crucial that our scientists, in complying with regulatory requirements, are not hampered by bureaucracy (paragraph 7).**

4. **The HFEA's new emphasis on communication with the public is welcome. Continued public confidence demands that the HFEA takes the lead in encouraging awareness and debate about research and treatment involving human embryos (paragraph 8).**

5. **The Prime Minister said recently that he wishes to avoid a "retreat into a culture of unreason". A good place to start would be to ensure that the Human Genetics Commission has access to sufficient funds to enable it to conduct an extensive and genuine dialogue with the public (paragraph 11).**

6. **We recommend that the Government conduct a thorough review of advice and regulation across the fields of medical genetics, embryology and reproductive medicine, with a view to producing a more streamlined structure (paragraph 13).**

7. **The Government should operate from the principle that no more advisory and regulatory bodies should be created than are absolutely necessary and it is better to reinforce the success of existing bodies by extending their remit than to spawn ever more small specialised bodies (paragraph 19).**

8. **We believe that the Government should remain active on the international stage, as well as domestically, in ensuring that scientific advances are facilitated yet appropriately balanced by regulatory and legislative control (paragraph 20).**

9. **The House of Lords Stem Cell Research Committee has identified several areas which might require new legislation. The Government should work on the premise that these developments will happen sooner rather than later and introduce legislation accordingly (paragraph 23).**

10. **Should the ProLife Alliance's appeal to the House of Lords be successful, we urge the Government to introduce new legislation to bring the creation of embryos by whatever means within the remit of the 1990 Human Fertilisation and Embryology Act (paragraph 24).**

11. The HFEA's decision to allow tissue typing in conjunction with preimplantation genetic diagnosis went beyond the scope of its own public consultation. It is vital that the public are taken along with decisions of such ethical importance (paragraph 25).

12. The Government's apparent reluctance to enact new legislation in this sensitive area has led to a position where the 1990 Act is open to legal challenge. We recommend urgent action to remedy this and reconnect the Act with modern science (paragraph 28).

PROCEEDINGS OF THE COMMITTEE RELATING TO THE REPORT

WEDNESDAY 10 JULY 2002

Members present:

Dr Ian Gibson, in the Chair

Mr Tom Harris	Mr Tony McWalter
Mr David Heath	Geraldine Smith
Mr Mark Hoban	Bob Spink
Dr Brian Iddon	Dr Desmond Turner

The Committee deliberated.

Mr Heath and Bob Spink declared an overseas visit to Germany from 19-21 March 2002 as a guest of the German Ambassador to discuss the ethical, moral and social issues surrounding emerging science.

Draft Report (Developments in Human Genetics and Embryology), proposed by the Chairman, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 28 read and agreed to.

Resolved, That the Report be the Fourth Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Ordered, That the provisions of Standing Order No. 134 (Select committees (reports)) be applied to the Report.

Several papers were ordered to be appended to the Minutes of Evidence.

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House.—(*The Chairman.*)

[Adjourned till Monday 15 July at Four o'clock.

LIST OF WITNESSES

Wednesday 24 April 2002

LIST OF APPENDICES TO THE MINUTES OF EVIDENCE

MINUTES OF EVIDENCE

TAKEN BEFORE THE SCIENCE AND TECHNOLOGY COMMITTEE

WEDNESDAY 24 APRIL 2002

Members present:

Dr Ian Gibson, in the Chair

Mr Mark Hoban	Dr Andrew Murrison
Dr Brian Iddon	Bob Spink
Mr Tony McWalter	Dr Desmond Turner

Examination of Witnesses

RUTH DEECH, former Chair, Human Fertilisation and Embryology Authority, BARONESS KENNEDY OF THE SHAWS, a Member of the House of Lords, Chair, Human Genetics Commission, and SUZI LEATHER, Chair, Human Fertilisation and Embryology Authority, examined.

Chairman

1. Welcome to our session and thank you very much for coming. We are informed that Baroness Kennedy is hailing it here from court so we will try and phase the questions to the Human Genetics Commission for her. We have been very concerned with these issues on this Committee in the past through stem cells and we had a session a month or so ago, talking to people who are dominant in the field, doing the research, asking them what might be the discoveries that come up that present us with regulatory problems and so on. We are very glad that you have come here to add to that investigation. Congratulations to you, Suzi, on your new appointment and, to Ruth Deech, well done for carrying the flag through some very difficult periods. Ruth, what have your organisation's main achievements been over your period in office?

(*Ruth Deech*) If I can start on a very broad level, the HFEA maintains the confidence of people and politicians; and in particular, when the very passionate debate on stem cells took place a year ago, it seemed to me that there was an implicit confidence in the strength of the HFEA and its ability to regulate and protect the public that gave Members of Parliament the confidence to vote for extended research and stem cells research. It was a question of maintaining confidence and a reputation, both nationally and internationally. That is on the broad level. On the narrower level, the HFEA moved with the flow of science to investigating and licensing many new developments that never would have been thought of in 1994 when I became chairman. The HFEA examined and coped with new developments like frozen eggs, more extensive use of intra cytoplasmic sperm injection, questions about multiple embryos, great increases in the number of embryos used and the types of treatments used. We moved with the science and the increase. Lastly, the HFEA perhaps with more difficulty had many more new requirements imposed on it which were to be expected with new attitudes towards governance, much more by way of paperwork, things like risk assessment, quality control, performance indicators and so on. Much of that was imposed on the HFEA latterly and, given the rather careful funding, higher expectations of that sort were quite difficult to meet.

2. It is often said that it is a cumbersome organisation in the sense that the paperwork keeps coming and it is caught up in bureaucracy. Is that true? Do you think that you have been caught up in the regulations and it has been a difficult organisation to get moving, to face up to almost a daily change in the science?

(*Ruth Deech*) We were more regulated against than regulating. The HFEA's policy was to regulate clinics and scientists quite minimally, requiring from them just what was necessary under the statute and in order to keep pace with the modern demand for statistics and after studies. What I found more onerous latterly were the requirements on the HFEA itself by way of paperwork. For example, we had two quinquennial reviews in the space of four years. For anyone who has done some Latin, that is quite surprising. We were always, maybe quite rightly, being held to account for one thing and another. The National Audit Office was looking at us; departments were looking at us. I thought the requirements on the HFEA were almost more onerous than what was required of the clinics. The policy ought to be as little paperwork as possible. I am echoing Baroness O'Neill's reflexures. There ought to be more trust and perhaps less paperwork all round. Sometimes, when there were brand new developments, brand new clinics and areas that were giving rise for concern, it was right for the HFEA to go in and require the paperwork but, in general, the aim ought to be that the departments trust the HFEA and the HFEA should trust most of the clinics.

3. Are you saying that you feel there has not been trust on occasion?

(*Ruth Deech*) I do not think there is a real lack of trust. The requirements are such that it feels as if there is a lack of trust.

4. Has that been frustrating for you, running the organisation?

(*Ruth Deech*) I would not say it was frustrating. I just think it takes up an awful lot of time. The HFEA dealt with many wonderful and interesting advances in science but probably 75 per cent of the time of its members and staff was taken up with purely regulatory matters, also very interesting, but growing in weight, with a very small budget.

Bob Spink

5. You have just talked about what Parliament intended when it set up the HFEA. I wonder if Parliament really did intend, when it set up the HFEA, that very onerous and fundamental decisions that make basic changes in humanity should be decided by the HFEA under that original legislation. We had a decision from the HFEA a few weeks ago to selectively, by genetic engineering, for the first time ever, give authority for the creation of a new human life for the specific purpose of benefiting an existing human life. That may be good or it may not be good. It certainly has enormous moral, ethical and social consequences, particularly for the new life that has been created that may have impacts throughout its life. It certainly sets a precedent and in this country things operate by precedent, so it was a very important, significant, new decision. Should that decision have been taken by the HFEA or should it have been brought back to the democratically accountable Parliament to be discussed? What do you really think about that?

(*Ruth Deech*) I think Parliament did so intend the HFEA to take those decisions. The statute rests on the report by Baroness Warnock of 1984, which remains unrivalled in its wisdom, depth and flexibility. Baroness Warnock and her team were wise enough to foresee that there would be very many questions of great complexity—there always are in science—that cannot be frozen in any statute of 1990. It is a very flexible, very cleverly drawn statute. The fact that the HFEA took that decision protects Members of Parliament from direct involvement in that sort of thing, which I may venture to say is right. It also protects the clinicians themselves from direct responsibility. It places that responsibility on a body of people who have been chosen after advertisement in the newspapers to do that task, so it is a democratic way of deciding those things.

6. You are now getting confused in your answer. How can it be democratic if you are preventing the democrats, the Members of Parliament who are elected to make difficult decisions on behalf of society as a whole, and protecting them from having to make such complex, fundamental decisions? You said that Baroness Warnock may have anticipated it. I do not think Baroness Warnock ever anticipated or Parliament in 1990 ever anticipated that they were giving the right to create new human life for the purpose of benefiting an existing human life. That debate was never had. I think it is time that debate was had and, in view of that and in view of the HFEA's decision, I would seriously question if the HFEA is still fit for its purpose, as it was established some 12 years ago.

(*Ruth Deech*) I would argue that it is fit for purpose and that it is acting exactly within the parameters of the statute that governs it. Baroness Warnock's report was foreseeing very many new developments, including that. I would not call it genetic engineering. The HFEA has spent many months considering the question. I would call it the preservation of life. We should remember that many parents, including the parents in this case, will have children naturally. There was the famous case of Nicola Horlick. People will have children naturally in an attempt to help save the life of an older child. It is just the umbilical cord blood which is normally thrown away which is used in that case, no more, no less. We felt pretty confident in making that decision and our understanding was that, like many other scientific bodies, we would make decisions that were within our remit under the statute and that are perhaps, with due respect, too detailed for Members of Parliament to debate on each separate occasion, given that cases like that are coming quite rapidly. Every week there is something new and, humbly, if I may offer the opinion, I think it is right to have an expert, democratically appointed body to take those decisions.

7. I am surprised that a person of your stature should fall back on the use of facile language to cover your embarrassment. It is almost like the killing of a child by abortion being described in some other way because people do not want to face up to the specific consequences of their acts. You said that this was not genetic engineering. This is precisely what it was. It was the selection of certain gene traits to give a particular outcome so that that child would be useful in helping some other child. I am not saying that is a bad thing. I am saying that this was a fundamental, life changing event. It broke new ground in the most fundamental, scientific manner and I am surprised that you should not accept that.

(*Ruth Deech*) My understanding of genetic engineering is that genes will be manipulated to produce some type of human being that was better in some respect than that which we have already. In the case of the Hashmis, the proportion was that one was likely to get one in 16 embryos of the embryos that were produced by Mr and Mrs Hashmi that would give a child that was not only free of beta thalassaemia but also matched the sick child. The public has been consulted about pre-implantation genetic diagnosis. The public came back saying that they did approve of it as long as it was carefully regulated so that families that suffered from an inherited genetic disease would be able to choose an embryo free of that disease. In a decent, caring, democratic society, scientific developments can be used for the good of all. If we look back, we do see that nearly all scientific developments have eventually improved our lot. If you lived in an authoritarian or dictatorial society, then you would have to be fearful that scientific developments will be put to the wrong use, but I am not embarrassed by the Hashmi decision. We thought about it for many months and we feel it was the right thing to do, that it was ethically desirable and it is limited only to cases where pre-implantation genetic diagnosis is already justified, which is that family suffers from a serious disease already.

8. Could we have on record that there was no public consultation on the case that I have raised?

(*Suzi Leather*) When the authority made that decision, they set eight conditions under which they would permit PGD with tissue typing. The eighth condition was that embryos should not be genetically modified to provide a tissue match.

Dr Iddon

9. As a scientist and now a parliamentarian, I sometimes have the feeling that technology is racing ahead of legislation and I am sure you get that feeling as well in making these difficult decisions. Do you ever get the feeling that the HFEA is holding up research or at least inhibiting the pace of it?

(*Ruth Deech*) I was a bit surprised by Mr Spink's question because usually we are told that we are holding up matters rather than facilitating them. Given that there was criticism from both sides, I think the HFEA was doing it about right. Those who launched on new types of investigation knew that they would have to face peer review, review by a committee of the HFEA and that new developments would not be rushed into public use without very careful scrutiny as to their safety and viability. Given that delegations have come from countries all over the world to see how the HFEA do things, given that Britain is ahead of the world in stem cell research and in many other fields, I think it is no coincidence that British advances in science and the confidence in them go hand in hand with very tight regulation.

10. Do you think you process applications slowly, because that has also been a criticism.

(*Suzi Leather*) In licence decisions, we process them on average in four months. I do not know whether you think that is slow or not. The procedure does include peer review. I think four months gives applications due weight and proper investigation. If we hurried them through faster than that, we probably would not be doing our job properly and if it was taking much longer than that there would be an issue about holding it up.

11. I do not judge the applications. Do you feel that you are under criticism from the people who do?

(*Suzi Leather*) It is both the case in science and in regulation generally that services do not always welcome the action of regulators in terms of establishing public confidence it is proper that we always go through due process. To ensure cautious allowance for the due process I think four months is about right.

12. Turning to resources, I have a figure of 1.5 million and 30 staff involved in the HFEA. I do not know whether you want to contradict those figures but do you think your budget is adequate at the moment to do everything you are being asked to do by central government?

(*Ruth Deech*) I feel it was not, certainly towards the end of my chairmanship. The budget stayed at one point something million for many years and if the HFEA were set up today, in the light of public fears about anything with the word "genetic" in it, whether it is BSE or genetically modified food or whatever, there would be a much more exhaustive approach. I believe that we have the least funding of any comparable organisation. While at the beginning there was not quite so much going on, it has become very difficult to cope with scientific advances, with the more than doubling in the number of treatments, with ever more stringent requirements about inspection of laboratories and so on, on the budget. It was very hard to afford to go to conferences, to get staff that were sufficiently properly paid and so on. Our staff were paid less than you would expect to pay highly qualified scientific staff in other comparable organisations.

13. Does that impinge on the quality of your staff?

(*Ruth Deech*) No. We have been very fortunate in getting, for example, young graduates, very often PhDs from universities, but we were not able to hold on to them long enough. Things have improved very recently, but it is a question of quite a small amount and it would be money well spent in order to satisfy the fears that might be expressed by parliamentarians and the public. There is a heightened expectation amongst politicians and the public that nothing should go wrong in this field. In a few years' time, teenagers will be able to inquire of the HFEA whether they were born of assisted reproduction and whether they are related to someone whom they propose to marry. In other words, there will be detailed inquiries of our register about paternity and we need to be able to handle those. No doubt the expectations will be even higher in a few years. In my view, the budget was inadequate.

Dr Iddon: What should it be?

Chairman

14. What is it going to be?

(*Suzi Leather*) As a newcomer, the HFEA is an organisation which has consistently punched above its weight in terms of what it delivers for the resources and it has delivered extraordinary value for money. If you look at an average of the first ten years of the HFEA, it received about £100,000 a year from government and the rest of its income from fees. I need to check this and get back to you but I think that took it up to an average of 1.4 million. Coming to this from new, when I first heard what the budget was, I thought they had got the decimal point in the wrong place because if you consider the enormity of the task in front of it, many members of the public, looking at how other regulatory organisations are funded, would be surprised that it was being funded on that sort of budget.

15. How do they compare with the Food Standards Agency?

(*Suzi Leather*) There is absolutely no comparison. The Food Standards Agency is a government department and employs very many people, 600, and indirectly, through the Meat Hygiene Service, a further 1,600. It is not strictly comparable.

16. They got a big budget to start off with, did they not?

(*Suzi Leather*) A very much bigger budget to start off with. I think it is fair to say that if the HFEA was being set up today it would be funded at a different level. Has that made a difference to the quality of the service provided? I think it is hard to say it has not made a difference. We currently have some IT problems with the register, which I am pleased to say we have just got some money from the Department of Health to help sort out, but it is clear to me that the main reason for that has been under-funding. I know a lot of organisations have IT problems. We could do more with more money. We could do more policy development work, for instance.

Dr Iddon

17. What should the budget be?

(*Suzi Leather*) I am coming at this very new and I think it would be wrong for me to pick a figure and say, This is what I think we need. Since I have become chair, I am pleased to say that ministers have approved a one of sum of £2 million this year to support the introduction of new technology for the registry system and that is hugely helpful, as will be the money to support our move, because the offices we currently have are rather strapped. If any of you want to come and visit them, you would be very welcome but there is certainly not room for me to have an office. That perhaps gives you some idea of the working conditions.

18. I am slightly concerned to hear Ruth say that among the things that suffer—you have mentioned information technology—was the inspection of laboratories and that could be quite serious if we were not inspecting laboratories where this work is going on in a serious way.

(*Ruth Deech*) I would not say inspection of laboratories. There were not so many and they were very thoroughly inspected, but there are almost 100 clinics that have to have an annual licence and they should all have inspection. We were encouraged quite recently to move to a lighter form of inspection in order not to bring the work of the clinic to a halt. On the other hand, all it takes is for one matter to go wrong and the pressure is to inspect that clinic more thoroughly. If I can go back to the budgetary question, I feel free to say this because I am no longer chairman. The latest calculations that would have produced a very good service and well paid staff and a good IT system before I left were more of the order of six million per annum which, in comparison with other similar organisations, is still not very much, but certainly not down at 1.9 million per annum.

Mr Hoban

19. Brian asked about approving the process of applications. Is it your approach to facilitate new applications for technology by setting the right licence conditions? How many times have you said no outright to something?

(*Ruth Deech*) Licences for research were approved provided that they fitted into, I think it is now, eight categories of research that are in the statute. There were five originally and two or three more were added a year ago. They were sent out for peer review first. The number of embryos that was likely to be used was always checked and questioned. The laboratory itself was inspected. The CVs of the persons involved were taken in. Comments were sought from scientific peers and a committee would meet in the HFEA to approve the licence. I cannot tell you how often they were refused but I recall several occasions where an application was referred back for more detail or changes in the purpose or further questions were raised or the licence was only granted for six months rather than for a longer period. Almost invariably, a further report was called for from the researchers after, say, six months or a year, in order to see what had been achieved and to make sure that what had been achieved lay within the boundaries of what had been approved.

(*Suzi Leather*) If it is helpful, we could give the Committee some more detail on that.

Chairman: Thank you.

Dr Turner

20. You have already faced some reasonably tough challenges in your existence but what do you think about the challenges that are most likely to hit you in the future? What do you think will be the big ones?

(*Suzi Leather*) I am only seven weeks into this job so I am still very early on the learning curve, but let me give you some first impressions. When I came in, I asked myself three questions. One, is the HFEA doing a good job? Secondly, is that likely to continue? What is the read forward in what we are doing? Thirdly, do we need to be doing anything differently? On the first question, are we doing a good job, I think Ruth has covered that very admirably. The HFEA is highly respected, not only in this country but internationally. It is increasingly looked to as the model for regulation in this field. If I might take this opportunity of paying tribute to Ruth and to Sir Colin Campbell before her, a great deal of that is because of the leadership shown by Ruth and Colin. It is a very difficult job and they have both done it extraordinarily well. It is also due to some pretty good legislation in the first place. It clearly reflects the strength of the UK science base and that would be an issue for this Committee. In terms of public perceptions, there is probably very little detailed understanding of the work that the HFEA does and a great deal of that comes from the press. I think the level of understanding of the procedures that we are regulating is probably quite low. For instance, a taxi driver asked me what the HFEA did and I explained some of the micro-manipulation techniques. His answer was, "Cor blimey, whatever happened to the birds and the bees?", so there is quite a gap potentially. Is this job likely to continue? There have been very significant changes since the HFEA started. Certainly the science is very fast moving but there have also been changes in the public expectations about openness, accountability, consumer demands for information. The whole issue of how science progresses and how the public gives consent to science is quite important. Do we need to do anything differently? What are the things that are coming over the horizon? Maintaining public confidence in the regulation of the fast moving area of science is quite difficult. What the public do not like are surprises. We learned that from GM. We have to keep the gap between what is happening and what the public knows about as small as possible. That issue of communicating what we are doing, communicating what the possibilities of science are, what the benefits and disbenefits are, is probably the core challenge for the HFEA.

(*Ruth Deech*) I would agree. It is very important to maintain confidence in the HFEA in order that stem cell research and whatever else lies over the horizon can be acceptable and properly governed. I also think that over the years the effects of the human rights legislation will have to work themselves out. Some of the decisions that we made very recently can be explained by our careful regard to the legal advice we

[**Dr Turner** *Cont*]
were given about human rights. That is going to become more difficult to stop people doing things when they are likely to rely on human rights legislation and on European legislation. Another challenge will be coordinating or at least finding out what is going on in Europe and how new legislation is going to affect the work.

Dr Iddon

21. Putting the religious arguments aside, do you think the general public are literate enough to understand the difficult arguments that prevail?

(*Ruth Deech*) Sadly, no. I think that British science education has not been very good. The newspapers do a fairly good job now of explaining things like, for example, Dolly the sheep and the effects of that, but like Suzi I have found quite a lot of bafflement if I have ever talked to a member of the public who knows nothing about this. Even when talking to others, they have very often misunderstood what they have read in newspapers and really know very little, especially about the more complex areas. I knew next to nothing when I started and I think there is a great need for public education. It is because of the poor science education of my generation in schools.

Chairman

22. Welcome, Baroness Kennedy.

(*Baroness Kennedy of the Shaws*) I am sorry I am late. I am in the middle of a murder trial at the Old Bailey.

Dr Murrison

23. Advisers advise and ministers decide. I wonder to what extent you think ministers have been able to side-step some of their decision making responsibilities by the presence of your Commission.

(*Baroness Kennedy of the Shaws*) The Commission came into being two years ago and there were some departments which did not see the Commission as being somehow a Commission which referred to them. I particularly would refer to the Home Office. We were quite concerned that, in making decisions about legislating for the use of DNA and the expansion of the retention of samples, for example, ministers in the Home Office did not at any stage consult with us about how they would do that and whether there would be oversight and so on. That did concern us. With regard to the ministries which have a direct relationship with us, the Minister of Science within the DTI and Philip Hunt inside the Department of Health, we found we have had very clear avenues of contact and that they have wanted to hear from us what the Commission's thinking is on all the issues that have been on our agenda. I have not found a sense of displacement. There was a moment when it was clear that there was a group being set up to look at practical implications for the National Health Service and we wondered what exactly its role was, but having met with senior civil servants in the Department of Health and those who were on that commission, it was clear it had a very restricted remit and was not looking at the moral, ethical issues which our Commission is engaged to look at and to make recommendations with regard to regulation. We are not discontented at all with the nature of our relationship with government but we are arm's length from government. We are advisers to government and sometimes government will hear us saying things that they will not necessarily want to hear. That is the nature of an independent commission.

24. To what extent do you think ministers avoid their decision making responsibilities for which they are accountable to Parliament by being able to rely upon your advice?

(*Baroness Kennedy of the Shaws*) It is fair to say that obviously there must be concern, in a democratic society, if there is too much hiving off of decision making to bodies which are not democratically elected, and I would share concerns that anyone might have about that. It is one of the things very dear to my own heart. Our Commission is not in the business of decision making. We come to very careful views with regard to the need for regulation, the ways in which we can protect citizens from abuses, invasions of their privacy and so on. We then make recommendations to government and government have to make the decisions. There will be times when governments may seek to suggest that it is the Commission that has made the decision. I in turn make it very clear that we are advising and that government has to decide. The ministers will make the eventual decisions and that will be made clear to them.

25. Do you feel the advisory and regulatory functions should be kept separate and, if so, do you think that is happening at the moment?

(*Baroness Kennedy of the Shaws*) I do think they are being kept separate at the moment and I have to always remind people that the position of our Commission is rather different from the position of the authority that deals with the HFEA because the HFEA has a role in deciding who is licensed, who is not and so on. We do not have a role like that. Our position is to advise and then government decides how to regulate. We will give suggestions as to how that could be done effectively and we hope they take our advice.

26. I wonder what your views are on the introduction of confirmation hearings for appointment to government bodies by select committees?

(*Baroness Kennedy of the Shaws*) It is not something I am averse to. There has to be real openness. I have always been a campaigner for openness in government. As soon as I became chairman of this Commission, I made it very clear that I wanted the Commission to be conducted as openly as possible. One of the problems with the whole issue of science, I felt, was about a loss of trust. One of the ways that you inculcate trust is by conducting your business as openly as possible and showing that you are independent. We have made a decision—and it was not an easy one to get through; people had to be persuaded—that it was good to conduct everything openly. Some people had reservations. They felt that on a commission you may want to have discussions which should be in private.

[**Dr Murrison** *Cont*]
I felt it was very important, given how crucial this is in terms of public debate, that at this moment in time there is very open discussion on genetics. We decided after consideration that this Commission should sit publicly. All our minutes are on the website. We invite the public in to be present at our meetings and to hear our discussions which are conducted openly. The agenda is on the website and we conduct as many public meetings as possible. We have a sort of road show where we take the meeting out of London. We have been to Newcastle, Edinburgh, Cambridge and we are going to Manchester in a few weeks' time and we are going to Belfast later in the year. The idea is that we take this to where the people are who are interested in these issues and give them the opportunity to engage with the Commission. We have also set up a consultation panel. We have 106 people in direct link to the Commission, using the internet, who are part of a consultative panel of people whose families have genetic traits, so that they can interact with the Commission. The idea is that in this area you need very open processes. Anything that can add to that openness I am very keen to look at. In our Commission, all the appointments have been made using the Nolan principles. I applied for the job of chairman. I was in competition with others. I was interviewed and appointed by the chief scientist and others who were on the interviewing panel. I think I persuaded them that I was robust enough to resist pressures of all kinds, which I have a reputation for.

27. Do you think confirmation hearings would increase the level of openness or do you think they would be unnecessarily bureaucratic?

(*Baroness Kennedy of the Shaws*) It would be worth looking at for important roles. It could become bureaucratic if you did it for every position but there are some roles where public confidence is so important that you might want to look at it. For serious, big quangos, that might be something to look at.

28. And a quango such as yours?

(*Baroness Kennedy of the Shaws*) I would be happy to be confirmed in a public way.

29. It could be that you might feel you had more of a mandate were you to be subject to such a hearing.

(*Baroness Kennedy of the Shaws*) It is certainly not something I would have any resistance to and there are lots of other roles in public life where one thinks it would be good if people did have some sort of confirmation that this was what the public wanted to see rather than people who are just chosen by ways that are not publicly examined.

30. Suzi, as somebody who has just been appointed, I wonder if you would welcome that?

(*Suzi Leather*) I would welcome it for two reasons. I think it would increase public confidence and there is an issue of principle and openness. I would support it. If you want to use this as an opportunity to ask any questions, I would be delighted to help you in that respect. The openness and the communication of science that Baroness Kennedy has talked about is hugely important in establishing public confidence. The HFEA has not been a particularly open organisation. There are some important reasons for that to do with patient confidentiality, for one thing, and the Act itself makes it quite difficult to be open about a lot of what we do. However, I am very keen that we move towards a more transparent system. This summer we are launching, for instance, a public consultation on sex selection and I hope we will have public meetings as part of that. I am very admiring of the kind of things that the HGC has done. They are expensive to do and that has probably been the other, highly limiting factor in openness for the HFEA. In terms of research, I think there are certain almost costless things you can do to help public confidence. I would be looking, for instance, on our website to publicising the research that we have approved, and, importantly, an abstract which the researchers lay out: what are the public benefits that they see coming from that kind of research? I think, in order to generate more confidence in science, the public need some signposting of where the science is going, particularly where public money is used for science. It is absolutely justified that the public should see what the benefits and the disbenefits might be.

Bob Spink

31. The HFE Act is ten years old now. It was updated last year to enable the use of embryos for stem cell research. Is it time it got a major overhaul?

(*Ruth Deech*) There are some areas which could be overhauled to take account of two things. One is human rights legislation and the other is that, in my view, there is too much confidentiality laid down in the Act. For example, no one can get in directly to repair our computer because of confidentiality. It is very hard to get outside, expert advice. It is very hard to do or to authorise follow-up studies because there is excess confidentiality. Baroness Kennedy will know that I took the same line at the HGC. I think it would be a mistake now to put down too much confidentiality for the future because we need to know the results of what we are doing and we need follow-up studies.

32. What are the areas in existing legislation that you would like to see changed or tightened?

(*Ruth Deech*) There is nothing that I would like to see changed or tightened. The procedure for appeals needs looking at from a human rights point of view. I would relax the confidentiality provisions but the structure remains pretty good.

33. Do you feel that introducing new legislation could put a block on activity? Could it hamper the progress of valuable research?

(*Ruth Deech*) There is always a danger, when this subject is introduced in Parliament, so I have been told, that it could all become enmeshed with opponents of abortion and other such issues. That may be a reason why the Act, which I said earlier I thought was good and flexible, has not been much touched in the last 11 years because one does not quite know what attitude will be taken. There is a risk if one reopens the issue.

34. I am sorry if I was very firm with you but I think the record will show that it was useful. In taking that decision, did you receive any advice from ministers?

(*Ruth Deech*) No.

Dr Turner

35. Baroness Kennedy, the Committee in the previous Parliament recommended that the Human Genetics Commission should monitor the use of genetic testing by insurers. I would like to know what progress you have made on that and whether you have detected any breach of the moratorium on the part of insurers.

(*Baroness Kennedy of the Shaws*) I am happy to say that we have no evidence yet of any breach of the moratorium. Having had that request by this Committee to monitor what was happening, you will have seen that we responded very quickly and held the toes of the insurance industry to the fire and managed to produce a moratorium fairly speedily and one in quite wide terms. At the moment, we feel content that that is operating, but we are looking very closely at how it is going.

Mr McWalter

36. The House of Lords Stem Cell Research Committee has suggested the establishment of a "body with oversight of clinical studies involving stem cells, or extending the membership and remit of GTAC to achieve the same ends" and "endorses the Department of Health's proposals to establish a stem cell bank". Do you think that a new body is needed to regulate research on stem cells or should GTAC do it?

(*Suzi Leather*) What is proposed is sensible. From the HFEA point of view, the Lords draw attention to the fact that this will be an increased area of our work, although I know it is the view of the Department of Health that it is not going to make a major impact on what we do. It is difficult to say at the moment how burdensome our aspect of stem cell regulation will be. We are only responsible for pulling out the stem cells from the embryo and ensuring that they then get reliably, traceably deposited in the stem cell bank. That, at the moment, is taking up quite a lot of work. We have two or three people working between a quarter and a half of their time at the moment on the issue of stem cells. We are having a piece of work done to evaluate what the impact of the regulatory burden of the stem cell work will be for the HFEA. Of course, we will have to increase the peer review capacity but from our point of view it is really the issue of joined up regulation between the HFEA and whoever has oversight over the stem cell bank.

37. You are saying you would like to do it yourselves?

(*Suzi Leather*) No. I am sorry if I gave that impression.

38. You would welcome which? A new body or GTAC extending their role?

(*Suzi Leather*) I am only going to express the view that whoever has responsibility for stem cell regulation for the bank, as far as possible, acts in an open way and communicates to the public what the benefits of doing this work are. From our point of view, it is very important that we establish good, joined up regulation in this field. I am certainly not arguing for the HFEA taking over all responsibility for this.

39. What about the HGC?

(*Baroness Kennedy of the Shaws*) We feel there has to be an independent body. It should be transparent. It should be of people with real expertise in what kind of research is really going to produce valuable results, because there is a balancing act as to the benefits to society that will come from any research as against the scruples and reservations ethically. We want to see a body which is independent, open and which has the kind of expertise which will really recognise where this research might be going.

40. The House of Lords thought you should both have an impact to this process and you would welcome that. Do you think you have the expertise to get that body moving?

(*Baroness Kennedy of the Shaws*) On my Commission there is enough expertise. We have a number of very highly qualified scientists in this field, including Sir John Sulston who led the genome project at Cambridge, and other geneticists. I would have thought that we could certainly contribute some real expertise in the creation of that body.

(*Suzi Leather*) At the moment, I am satisfied that we have the capacity to do it. We have, as the Lords have suggested, to keep an eye on the regulatory burden of our stem cell work so that we have adequate resources to cover that, should it turn out to be quite a large area of responsibility.

41. Do you work together or is this the first time you have met this year?

(*Baroness Kennedy of the Shaws*) The HFEA has representation on my Commission and Ruth Deech has been that person since its beginnings. Suzi Leather will take Ruth's place from now onwards. We are very closely connected and we engage on these issues all the time.

42. Your view would be that this new body would be both responsible for regulation of stem cell research and for the oversight of stem cell banks. Is that right?

(*Baroness Kennedy of the Shaws*) Yes. I think it could have that dual function very easily.

43. You are all happy about that?

(*Ruth Deech*) Yes.

Dr Iddon

44. Can I ask the HFEA how they use overseas expertise and indeed how you monitor the regulation and advisory processes in other countries?

(*Suzi Leather*) We do use, in our peer review process, people from outside the United Kingdom. I am very keen that we extend that. That enables more confidence within the scientific community as well as within the public. We have recently added five people with expertise in the stem cell area to help us do the reviews in that.

45. You are in touch with all the regulations that are going on in the rest of the world as they change or come into place?

(*Ruth Deech*) There are not that many, to be honest. It is more the other way, that people in the rest of the world are looking to us. The regulation in the rest of the world is very patchy. There is next to nothing in Italy. Central Europe is rather stricter.

[Dr Iddon *Cont*]
There is some communication in France but in my time a delegation was summoned from the HFEA to give evidence to the National Assembly in Paris. The HFEA was summoned to Japan and various other places. It was largely a one sided process. There is next to no regulation in the States either so it tended to be the HFEA advising the rest of the world, but we do have some resources as to what is going on there. There is great disparity.

(*Suzi Leather*) Recently, the Canadian Government has looked to the HFEA as a model and our chief executive went out to Canada to advise the Canadian Government on our model.

46. Are you keeping an eye on the question of developing international regulation in this area?

(*Ruth Deech*) There are such grave cultural and religious differences between countries that it is quite difficult. Those international treaties that do exist are of a very vague language. We all agree that there should be no reproductive cloning but many countries have no laws to stop that. I think it is going to be very hard. Our finances were such that the HFEA could not afford, except very rarely, to send anyone to an international conference, so we were reliant on people coming to us or, if I was funded by a university, I could go but financially it has been quite difficult to go unless foreign countries have paid for us to go to them.

Dr Iddon: We have met this conflict in Europe where there is a great difference between the southern European members and the northern European members.

Mr Hoban

47. Can we talk about consultation? Suzi, you said communication is the core challenge for the HFEA and you said that you had not been particularly open in the past. With those thoughts in mind, how do you see the development of consultation processes for sex selection, given that that is a very sensitive area for a lot of people?

(*Suzi Leather*) You are right; it is a very sensitive area. We have a limited amount of money to spend on this, £48,000, which does not buy a great deal of public process. Nevertheless, we are currently drawing up a consultation which will happen this summer. We are due to report to ministers by the end of the year. As part of that, I would want to have as much public debate about this as possible. I do not know if anyone saw the programme on television on Monday night but I am very glad to say that that covered this issue of sex selection. There are huge ethical issues involved in the new mechanisms that have been developed in the United States for sorting sperm that is going to create male and sperm that is going to create female babies. There are also straightforward safety issues and consumer issues: how reliable is this technology? The ethical issues and the welfare of the child issues will always be the most important ones.

48. When you consult, are you presenting a balanced case or a case that is loaded one way or the other?

(*Suzi Leather*) Absolutely not loaded, no. We are interested to know what the issues are for the general public and where the balance lies. In 1993, there was a public consultation on sex selection which approved the use of sex selection in order to avoid serious, sex linked diseases. The view of the general public at that time was that using sex selection, for instance, for family balancing was regarded as too trivial to be permitted. It would be interesting to see whether public views have changed.

49. Baroness Kennedy, you referred to your public consultation programme. Is that an education programme or is it a listening programme?

(*Baroness Kennedy of the Shaws*) We see it as both. Part of it is about consultation to make sure that we are in touch with the Zeitgeist, how people are feeling about many of these issues, but inevitably the way that it is conducted involves many people in the learning process, as indeed it did for me joining the Commission. We usually have a presentation or sometimes a film to stimulate the debate. It ends up being both because people are learning by virtue of the nature of the debate.

What is the budget for your consultation programme?

(*Baroness Kennedy of the Shaws*) We did a similar thing on "Whose hands on your genes?" but we did a consultation on the privacy issues around genetics and that cost us in the region of about £50,000. We used the People's Panel which is quite an interesting way of seeking to do this. A couple of years ago, the People's Panel was established which gave you some cross section of the public and it was to be used for this kind of purpose, so we found that was quite a useful way of getting a test on some of these issues. It threw up quite interesting responses as to what concerned the public.

Chairman

51. Let me ask you about the Green Paper on genetics that we hear is coming along. Are any of you playing a part in the production of that? If not, what do you think should be in it that we do not know already that is contained in a million other papers that we have all read over the last year or so: ethics, morality, what genes are and so on. Can you see a justification for it?

(*Ruth Deech*) There may be a danger of overlap and duplication, possibly. The Government did review the offering of scientific advice in a White Paper a few years ago and brought together the existing committees roughly under three umbrellas. I think it would be as well to stick to that format. As many reports as one gets, I suppose, will produce different answers.

(*Baroness Kennedy of the Shaws*) I believe that the idea behind it was about the very thing we are discussing, which is trying to create public debate. If there was a Green Paper, it could become the basis for a much more public debate. I have met with those involved and they have consulted with us and they have been kept abreast of what our work is, so they are keeping a close connection in that way. One of the major concerns—and the Green Paper is particularly addressing it—is how does this impact on health care

[**Chairman** *Cont*]
provision within our society. What will the impact be on the National Health Service, for example? There are very serious considerations where you do have to horizon gaze and look at how you bring this into considerations of all sorts of things, including training. It is about trying to think about this ahead of the game, how you train professionals for counselling and so on.

52. Suzi, have they roped you in yet?
(*Suzi Leather*) No. I have not personally been involved in this.

53. In the massive experience you have had in this field over the last few years, do you see a gap that we need somebody to say something important about? Is it all there somewhere if we just dig it out on the internet or some other way? Is there anything you have picked up in your experience that is missing?
(*Suzi Leather*) The gap is the open process. I do not think it is easy to fill that. We all have to change the way we operate and we all have to be more open and transparent. The issue of horizon scanning is quite important and that is something that perhaps the HGC and the HFEA could work on together in the future. The public needs to be signposted on scientific development. They do not like being surprised. In order to have confidence in the regulatory process, we need to present regulation as being one step ahead, or at least keeping up with scientific developments, not one step behind.

Mr McWalter

54. When we talk to Danish parliamentarians about some of these issues, they cannot do any genetics research because there is a substantial Christian community which, the moment you open it all up, closes it all down. The cost of openness might well be inactivity. Have you considered that that might be one consequence of where you are going?
(*Suzi Leather*) The area that I have been most closely involved in until this time has been in food and agriculture. What I see has been the huge damage caused by confining debate to experts and scientists and by keeping a gap between what they are talking about and what the public knows about. The public does not like to be surprised. The public can understand complex issues as long as you communicate clearly what the benefits and costs are.
(*Baroness Kennedy of the Shaws*) The cost of secrecy is far greater. The cost of closure, the cost of not having open discussion, is much greater than ever it could be about opening it up and being prepared to argue in the market place of ideas what the benefits are. Our experience has been that, on the one side, there is concern about some of the developments here, but the general public want to travel hand in hand with scientists on this. They want to be kept abreast of what is happening and they want to make sure that regulation takes place where it is required as we are more informed about what is taking place. There is a great deal of genetic altruism and goodwill out there in society, where people do feel that the benefits from this may be considerable; but as long as there are sufficient protections against abuse there is a will for possible cures and so on to be investigated. They really want it carefully monitored and they want to have trust in the bodies which are engaged in this process of advising government. Establishing that trust is one of the challenges facing a Commission like mine.
(*Ruth Deech*) Britain is a much less religiously polarised country than many of the ones that you may have visited in your quest. Religious issues on the whole were not brought to us. The other thing is that at least one gets a female point of view in the use of committees like ours. I think it is no coincidence that all three of us here are female and that way you will get the female voice which I do not think has been very frequently heard in Parliament in its discussions on genetics and reproductive matters.

Dr Murrison

55. Helena, in December 1999, the HGC took over the functions of the HGAC, the ACGT and the AGSAG. You now co-exist with the HFEA. Obviously, there is a great deal of working between organisations and I suppose the fact that you took over the functions of all those separate august bodies demonstrates that. We have heard today that there is a great deal of work that goes on between you. Do you think there is any danger in that? Do you think there may be too much overlap of your working or not?
(*Baroness Kennedy of the Shaws*) No. I think sense had to be made of all those different committees. There you were, having to unravel areas of overlap and bringing a Commission into being was a very sensible move. Even still, there are bodies out there working on this who are making a very valuable contribution to the thinking on these processes, whether it is this Committee or a Committee in the House of Lords, the Nuffield Foundation. Lots of different bodies are here with their fingers in this area. I am not alarmed and I do not feel there is too much overlap. We are quite clear about where the overlaps exist and we have got them fairly well worked out. We collaborate in a sensible way. We are fairly distinct and I am happy we are so distinct because it means some of the more difficult issues are over here with my colleagues to my left.
(*Suzi Leather*) It is a benefit to the HFEA that the HGC can have a bigger look, and does have a good resource base for doing the public consultation, because our primary focus is regulation. Of course we have a kind of advice role as well and that is important. We will always be closer to patients and closer to some of the health consequences. We will always have people knocking at our door saying, "We want to license this. Can we have a licence for this?" but it is very helpful to have the HGC with its distinct role.

Bob Spink

Would you be prepared, on your international dimension, to meet with visiting committees from abroad—for instance, the German Ethics Committee or Council? Would you be prepared to see them if they came over and wanted to see you?
(*Suzi Leather*) Absolutely. Our door would always be open.
(*Baroness Kennedy of the Shaws*) Absolutely.

Dr Iddon

57. Baroness Kennedy, do you think your resources are adequate for the job you are being asked to do?

(*Baroness Kennedy of the Shaws*) Never!

58. I have a figure here of £250,000. I do not have a figure for how many staff that employs so perhaps you could tell us how many staff are employed and what that figure of £250,000 should really be. That is the 2000/01 figure.

(*Baroness Kennedy of the Shaws*) We have a wonderful secretariat. The bulk of our money goes into having meetings and taking them to different parts of the country and having them in public. We would like to do that even more and have bigger public meetings where you can have this real public engagement. As was said earlier by Suzi, for that you really do need resourcing. We could do that even better and we are acquiring some skill at it but we would like to do it even more effectively and perhaps even more frequently. We do not have the money so I would like more resourcing, please. There are three members of staff from the Department of Health, one from the Office of Science and Technology, so four staff members on our secretariat.

59. Have you ever asked for more money?

(*Baroness Kennedy of the Shaws*) I am one of those people who, whenever I see a minister, never misses the opportunity of saying that we could do with more money.

60. Have you ever put a figure on it?

(*Baroness Kennedy of the Shaws*) At the moment, we are wanting to put very solid figures on the kind of public meeting we think we would now like to move to. We are working on getting clear figures for that so that I can be even more determined in my efforts to get money.

(*Suzi Leather*) Last year, our total income was just under £3 million and we have a staff of 40.

Chairman

61. What is the next headline going to be? Is it going to be pre-implementation diagnosis that excites *The Sun* and *The Mirror* and the others? What do you foresee coming up?

(*Baroness Kennedy of the Shaws*) We are about to have published two books, one by Francis Fukiyama, who wrote *The End of History*, and he has written a book which is a shock, horror book about the post human era, about the creation of a super human being who will live 150 years, who will be able to defy disease and have implantations of genes which will keep him going for ever and the fears that will come with all of that. We will have quite a lot of frightening headlines around the debate that he will be having with an eminent American scientist who takes the other course which says that the genie is already out of the bottle. There will be human cloning. This is where it is all going to end up. This is what civilisation is about and we will just have to deal with it as it comes. That debate is about to take place in the next few months and I suspect it will lead to lots of headlines and we will all have to deal with the backwash that will come from it.

62. And your experience, Ruth?

(*Ruth Deech*) I think it will be to do with cloning. Dolly has arthritis and possibly worse. There may be bad stories about the dangers of cloning and that may be coupled with a botched attempt, but I hope no attempt, by the totally unregulated Signor Antinori of Italy to clone. In a way, that may highlight the advantages of having bodies like the HGC and the HFEA. We are in for a round of bad stories about cloning.

(*Suzi Leather*) Ruth is right. There will be wild claims of cloning, almost certainly untrue, but they will underline the importance that we have already in this country made it against the law and punishable with a long prison sentence. It is helpful to be able to tell journalists that when they ask us questions.

(*Baroness Kennedy of the Shaws*) The Human Genetics Commission is about to present a report to government on the issues of privacy. One of the issues which I think this Committee may want to look at is whether we should not be at an early stage looking at the need for criminal legislation for abuse of DNA. By that, I mean people obtaining it without proper consent, authorisation or by deception. It may be that we will have to urge government to legislate against people doing that. It is something that we can anticipate is a fear that people have and it is something we might see.

Chairman: Thank you very much indeed for coming and sharing your experiences and your prognostications with us. We are very concerned about genetics and the effects of regulation and the public consciousness and so on. We share that with you. I am sure the Committee would like me to thank you for the enthusiasm you have shown about the very difficult arena which involves everything right across the board from the new science to how we legislate and so on, and indeed, perhaps most importantly, taking the public along with us. It is quite clear that many of the problems we have been looking at you have identified too and I am sure, with teams like you, science is in good hands and we give you all our support in your efforts. Hopefully, we will see you again in the future. Thank you very much for coming along today.

APPENDICES TO THE MINUTES OF EVIDENCE

APPENDIX 1

Memorandum submitted by Professor Robin Lovell-Badge, National Institute for Medical Research

HFEA

The HFEA does a very good job given the level of funding they receive. There is some criticism of the length of time they can take to review an application or an amendment. There is also some worry that there is not enough basic science represented on the HFEA. I have been told that dealing with the HFEA is sometimes very frustrating for an applicant, because the submission is often done blind, so there are inevitably a lot of changes that need to be made. This is different, for example, to Project Licence Applications for research on animals, where the Home Office Inspector often meets with the applicant at an early stage and at times throughout the writing process, which helps to speed things up and ensures that the submitted application is free of significant problems. However, I can quite understand that the HFEA cannot do this, without substantially more personnel and funding.

Many other countries look to the UK and the HFEA to see how research and practice in this area can be regulated. Japan, for example, seems to be largely modelling its regulatory system on the HFEA, although there are some differences, eg how consent is granted, which are perhaps not well thought through, but I suspect this is line with other consent issues there. China is also modelling its guidelines on embryonic stem cells on the UK system (although these may well be a set of rules, rather than an HFEA type regulatory system).

Again, coming back to the financial situation of the HFEA, their level of under-funding could be seen as embarrassing if other countries are looking to us as a model of how work in this area should be regulated. It is clearly not sufficient money for the HFEA to be doing all they would want to do, and probably should be doing, to both regulate and inform the public, etc, about their business. In addition, I am not sure how well the HFEA is informed about scientific developments or about what is going on in other countries in terms of regulation, etc, but I strongly suspect this is inadequate. There is a huge amount going on.[1] More funding would enable them to attend meetings, as they themselves suggest. Again, it would be embarrassing if they are not well informed, especially if other countries are looking to us to set the lead.

HGC

The HGC does an excellent and very important job. It seems much less in the limelight than the HFEA and is consequently less well known as a body. It too seems very under-funded for its remit.

Stem Cells

The HFEA certainly could not, and in my opinion should not, be regulating work with stem cells. Nor do I think the HGC should be doing this. Both of these are really quite specialised in their area of expertise. Work with stem cells involves knowledge of several disciplines in addition to knowledge of reproductive biology and genetics. These include embryology, stem cell biology, perhaps tissue engineering and a wide range of clinical disciplines. Any body set up to regulate research and therapeutic use in this area would have to have to incorporate specialists in all of these areas, in addition to people who can cover ethical and legal issues. For the clinical aspects such a body would have to have a list of experts who could be called upon.

Both the HFEA and HGC could (and probably should) have an input into setting up such a body, but this would also need to involve the Research Councils (especially MRC and BBSRC), medical research charities, the NHS, etc. The problems will first be getting everyone to agree on how it should be set up and what its remit is, and then to create a body that is not too cumbersome, which can make sufficiently rapid decisions.

(N.B. This would be more similar to the HFEA, in that it would be making decisions, and less like the HGC, with its advisory role.)

Stem Cell Bank

The MRC is making good progress on setting this up. A stem cell regulatory body could oversee this, but it could also run independently.

June 2002

[1] I know of others who are trying to gather information with respect to the legal system and regulation of research on embryos, etc, in various countries. It is not easy, especially as laws are constantly changing. In theory these people could advise the HFEA, but they may be funded only for a short-term project, whereas it almost needs a permanent group.

APPENDIX 2

Memorandum submitted by Dame Anne McLaren, Wellcome Trust/Cancer Research UK Institute of Cancer and Development Biology

I was most interested to read the transcript of the discussion that you had with Ruth Deech, Suzi Leather and Helena Kennedy.

I feel quite strongly that the HFEA's responsibility for human embryonic stem cell research should be confined to the actual derivation of stem cell lines from human embryos. Further responsibility, for example for directed differentiation or for genetic manipulation for purposes of gene therapy, would be better lodged with a body that could eventually have oversight of clinical studies, for example the Gene Therapy Advisory Committee, at least when the cells have reached the stage of being tested for treatment. During the research phase, the Human Genetics Commission will no doubt have an interest.

A somewhat similar situation arises over surrogacy, where it was proposed at one stage that the HFEA should take responsibility, but it was really not within their remit and would certainly have overloaded their staff.

Since the HFEA seems to have a wider sphere of responsibility with every year that passes, they may in the future need more external expertise on their advisory committees and working groups, for example in horizon scanning. In my view this would be better than enlarging the size of the Authority which works well at its present size.

June 2002

APPENDIX 3

Memorandum submitted by Suzi Leather, Chair, Human Fertilisation and Embryology Authority

Thank you for your letter of 10 May requesting further information on points raised when I gave evidence to the Committee on 24 April.

1. From 1991 to April 2001 (the latest date for which information is available) the HFEA had received 152 applications for research licences. Of these 135 were granted and 17 were rejected.

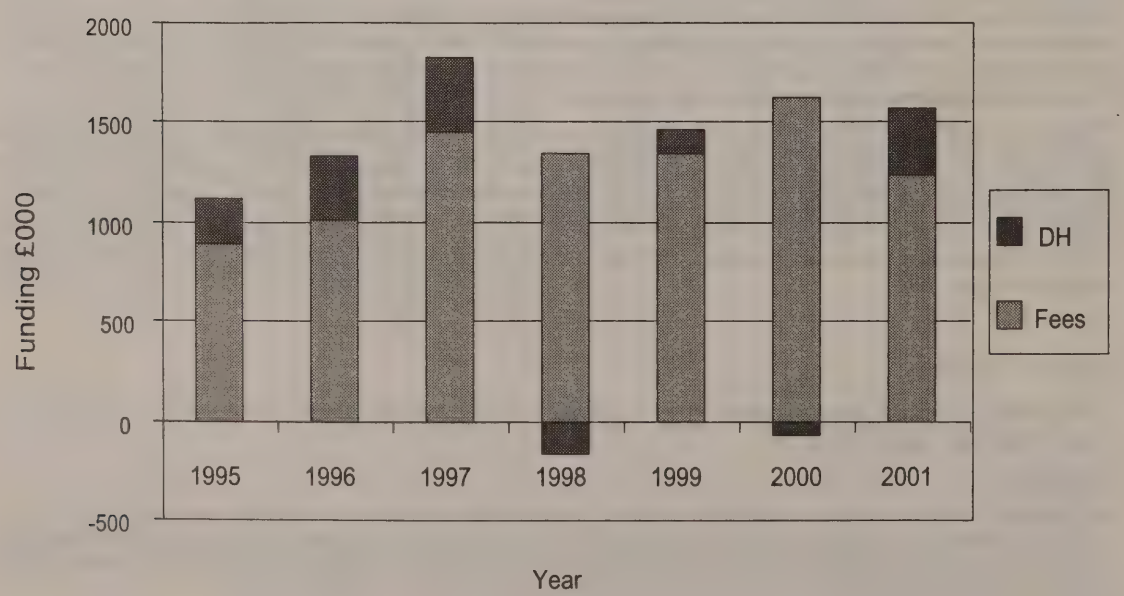
2. The HFEA will respond to the forthcoming Green Paper on genetics when it is made available for comment.

3. Please find enclosed a copy of the most recent accounts as they appear in the Annual Report 2001. I have also enclosed a table that shows the income derived from licence fees and that received from the Department of Health since 1991.

May 2002

Annex

HFEA Funding



HFEA FINANCIAL HISTORY (£000) SOURCES OF INCOME

	Year ended March													
	1991	*1992*	*1993*	*1994*	*1995*	*1996*	*1997*	*1998*	*1999*	*2000*	*2001*	*Total since 1991*	*Total past seven years*	*Average past seven years*
Actual HFEA licence fee income	0	70	699	765	884	1,005	1,454	1,347	1,345	1,625	1,242	10,436	8,902	1,272
Actual DoH funding drawn down	113	749	311	239	240	329	377	−160	115	−69	333	2,577	1,165	166
Total funding	113	819	1,010	1,004	1,124	1,334	1,831	1,187	1,460	1,556	1,575	13,013	10,067	1,438
HFEA fees as percentage of total	0%	9%	69%	76%	79%	75%	79%	113%	92%	104%	79%	80%	88%	88%

APPENDIX 4

Memorandum submitted by Professor Austin Smith, Centre for Genome Research, University of Edinburgh

1. I hold an HFEA licence to derive stem cells from human embryos, to explore their use for therapy. I have a number of comments on the functioning of the HFEA and forthcoming issues that it will have to face.

2. The HFEA provides no guidelines for drawing up consent forms for embryo donors and gives no advice to the licence applicant. Also, the HFEA is liable to revise its opinion on a form's acceptability: I have had a form accepted on one occasion only for the HFEA to find fault with it subsequently. There is no evidence of any communication with local ethics committees. A consent form needs to be acceptable to the ethics committee and the HFEA and finalising a form can be a frustrating process. The HFEA should come up with a standard pro forma, after consultation with local ethics committees.

3. For research to progress, we will need stem cell banks with a wide range of cell types. Stem cell banks will need the force of law. At the moment there are few stem cell lines and all are in the hands of private companies. The HFEA seems to have had no view on this issue which is regrettable given the pivotal role it has in the creation of stem cell lines.

4. Because we may need a panel of embryonic stem cells for immunological reasons, e.g. from people with different ethnic backgrounds, embryos will also need to be created especially for research. We may need to prepare the public for this and the HFEA should play a role in this process.

5. While high staff turnover may be a factor, I have found HFEA's secretariat to be inefficient (my letters have been lost and telephone calls unanswered) and lacking in specialist knowledge. Unfortunately, the HFEA's committees seem insufficiently familiar with the science also. In responding to my queries, it seems that the HFEA looks to the Medical Research Council for specialist input, who in turn ask for my view, with the result that I am asked my view of a ruling which I am seeking. Research regulation seems to be at the margin of their activities.

6. In general, the HFEA is a slow and reactive body and a frustrating body to deal with. It effectively prevents inappropriate research but does nothing to facilitate appropriate research. The UK is in a strong position to be a world leader in this area of research and its applications. While robust regulation is important in such a sensitive area, this needs to be implemented without undermining the research. If underfunding is shown to be the cause of the HFEA's problems, I would welcome an increase in its expenditure limit.

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